

REMARKS

Reconsideration of amended claims 1, 3 and 5-7, and consideration of new claims 18-27 is respectfully requested. Claims 3 and 5-7 are amended to better define the object being claimed as not a composition but as the article of manufacture, that is, a consumer product that includes a bottle and a lens care solution contained within that bottle. Along these lines, Applicants request the examiner to consider new claims 21-27.

New claims 18 and 23 are supported in-part on page 3, paragraph [0007], specifically, lines 1-2. New claims 19 and 25 are supported in-part on page 12, paragraph [0029]. New claims 20 and 26 are supported in-part on page 9, paragraphs [0022], specifically, bottom of page 9 to top of page 10.

New claims 21 and 27 are supported in-part: page 3, paragraph [0007-08]; page 3, paragraph [0012], the data represented in Figure 1 and Table 4. New claim 22 is supported in-part on page 7, lines 1-3.

Applicants also request that the examiner consider the information contained within the Supplemental Information Disclosure Statement regarding the prior use in the United States of a poly(ethylene terephthalate) (PET) container and the use of the PET container to store and package a lens care solution, namely, OptiFree® Express, containing the cationic antimicrobial agent, polyquaternium-1.

The rejection of claims 1, 3 and 5-7 under 35 USC 103(a) as obvious over Groemminger (US2002/0115578) in view of Asgharian (US 6228323) is respectfully traversed with respect to the submission of additional experimental data in tabulated form below that demonstrates the advantages of packaging a contact lens disinfecting solution that comprises the recited range of PHMB and one or more of the recited surfactants in a PET bottle compared to packaging the same solution in a high-density polyethylene (HDPE) bottle. Applicants had previously submitted the data tables in a prior Amendment, however, as correctly pointed out by the examiner, the additional data was not formally presented with a 1.132 Declaration, and therefore, was not considered by the examiner. Accordingly, Applicants resubmit the data tables with the Declaration of Dr. David J. Heiler, one of the listed inventors, to correct this oversight, and

respectfully request that the examiner consider the unexpected results demonstrated by the data tables.

Applicants incorporate the comments presented in the prior Amendment for easy reference. Tables 1, 4 and 8 include the raw and mean initial time data for test solution 1 in PET and HDPE. Applicants recommend that the mean initial data in each of these three Tables be used to compare with the mean biocidal data reported in Tables 10 and 11 for each of PET and HDPE. In particular, Applicants direct the examiner's attention to the biocidal data related to *Fusarium solani* (Fs), which is included in Tables 10 and 11 for reference.

As indicated by the biocidal stability data, test solution 1 remains biocidal active in the PET container but not in the HDPE container. At three months, there is statistically no change in the biocidal efficacy of test solution 1 in the PET container. In contrast, there is greater than a 50% reduction in biocidal activity of test solution 1 in HDPE. Similar results are indicated with the biocidal stability data at six months for test solution 1 in PET and HDPE containers. There is about a loss of 30% activity of the solution in the PET container at six months. In contrast, test solution 1 is virtually inactive, that is, shows no statistical biocidal activity in the HDPE container at six months. Given this test data Applicants respectfully submit the examiner's *prima facie* case of obviousness has been rebutted, and request that the rejection be withdrawn.

Table 1. Log Reduction of PHMB Formulation in PET; Initial Time

Trial No.	t (hr)	Sa	Pa	Sm	Ca	Fs
1	1	3.6	4.5	2.5	2.6	1.8
	4	4.0	4.5	4.6	3.5	3.0
2	1	4.4	4.6	3.9	2.5	2.3
	4	4.9	4.6	4.7	3.9	3.8
mean	1	4.0	4.5	3.2	2.5	2.0
	4	4.4	4.5	4.6	3.7	3.4

Table 2. Log Reduction of PHMB Formulation in PET; 3 Months, 40 °C

Trial No.	t (hr)	Sa	Pa	Sm	Ca	Fs
1	1	4.6	3.7	1.2	3.0	1.9
	4	4.9	4.9	3.2	4.0	3.1
2	1	2.7	2.8	3.1	3.0	2.3
	4	4.6	4.6	4.6	3.6	3.2
mean	1	3.6	3.2	3.5	3.0	2.1
	4	4.7	4.7	3.9	3.8	3.1

Table 3. Log Reduction of PHMB Formulation in PET; 6 Months, 40 °C

Trial No.	t (hr)	Sa	Pa	Sm	Ca	Fs
1	1	4.7	3.9	2.2	2.8	1.8
	4	4.7	4.7	4.6	3.4	2.8
2	1	4.7	2.8	1.8	2.9	0.8
	4	4.8	4.9	4.5	3.1	1.7
mean	1	4.7	3.3	2.0	2.8	2.3
	4	4.7	4.8	4.5	3.2	2.2

Table 4. Log Reduction of PHMB Formulation in PET; Initial Time

Trial No.	t (hr)	Sa	Pa	Sm	Ca	Fs
3	1	4.6	3.4	2.6	2.9	3.7
	4	4.6	4.7	4.6	3.7	4.2
4	1	3.4	4.2	3.0	3.0	2.8
	4	4.8	4.6	4.6	3.8	3.9
5	1	4.8	2.4	2.8	1.5	1.7
	4	4.9	4.1	3.0	3.0	2.7
mean	1	4.3	3.3	2.8	2.5	2.7
	4	4.8	4.5	4.1	3.5	3.6

Table 5. Log Reduction of PHMB Formulation in PET; 3 Months, 40 °C

Trial No.	t (hr)	Sa	Pa	Sm	Ca	Fs
3	1	4.8	4.6	4.6	3.4	2.7
	4	4.8	4.6	4.6	4.4	3.9
4	1	2.5	4.7	4.0	2.9	1.9
	4	3.4	4.7	4.8	3.9	3.4
5	1	2.3	4.1	2.0	2.8	2.7
	4	3.6	4.7	4.7	4.3	3.7
mean	1	3.2	4.5	3.5	3.0	2.4
	4	3.9	4.7	4.7	4.2	3.7

Table 6. Log Reduction of PHMB Formulation in PET; 6 months, 40 °C

Trial No.	t (hr)	Sa	Pa	Sm	Ca	Fs
3	1	3.9	2.8	3.1	3.1	---
	4	4.9	4.8	4.6	3.6	2.6
4	1	3.2	4.4	3.3	2.9	1.0
	4	4.7	4.8	4.7	3.8	2.1
5	1	3.5	4.8	3.7	3.0	1.3
	4	4.9	4.8	4.7	4.2	2.8
mean	1	3.5	4.0	3.4	3.0	1.2
	4	4.8	4.8	4.7	3.9	2.5

Table 7. Log Reduction of PHMB Formulation in HDPE; Initial Time

Trial No.	t (hr)	Sa	Pa	Sm	Ca	Fs
6	1	3.5	2.4	2.2	2.3	1.2
	4	4.8	4.5	4.0	3.6	2.4
7	1	4.5	2.3	2.6	2.4	1.4
	4	4.8	4.0	4.6	3.0	2.2
8	1	3.1	2.5	2.0	2.6	1.9
	4	4.7	4.7	3.4	3.2	3.0
mean	1	3.7	2.4	2.3	2.4	1.5
	4	4.8	4.4	4.0	3.6	3.9

Table 8. Log Reduction of PHMB Formulation in HDPE; 3 Months, 40 °C

Trial No.	t (hr)	Sa	Pa	Sm	Ca	Fs
6	1	1.9	2.0	1.9	2.4	0.9
	4	4.3	3.4	4.0	3.1	2.0
7	1	3.4	2.3	3.2	2.6	0.8
	4	4.7	3.2	4.5	3.0	1.2
8	1	2.9	2.4	2.2	2.5	0.7
	4	4.6	3.1	4.0	3.1	1.3
mean	1	2.7	2.2	2.4	2.5	0.8
	4	4.5	3.2	4.2	3.1	1.5

Table 9. Log Reduction of PHMB Formulation in HDPE; 6 months, 40 °C

Trial No.	t (hr)	Sa	Pa	Sm	Ca	Fs
6	1	1.7	2.7	2.8	1.6	0.4
	4	3.1	4.5	4.1	2.2	0.5
7	1	2.0	2.4	3.3	2.1	0.5
	4	2.9	4.7	4.7	3.2	1.1
8	1	0.9	3.3	1.4	0.9	0.1
	4	1.4	4.6	3.3	1.4	0.3
mean	1	1.5	2.8	2.5	1.5	0.3
	4	2.5	4.6	4.7	2.3	0.6

**Table 10. Summary of Mean Log Reduction of PHMB Formulation.
3 months, 40 °C**

mean trial nos.	t (hr)	Sa	Pa	Sm	Ca	Fs	Fs t _o
1/2 PET	1	3.6	3.2	3.5	3.0	2.1	2.0
	4	4.7	4.7	3.9	3.8	3.1	3.4
3/4/5 PET	1	3.2	4.5	3.5	3.0	2.4	2.7
	4	3.9	4.7	4.7	4.2	3.7	3.6
6/7/8 HDPE	1	2.7	2.2	2.4	2.5	0.8	1.5
	4	4.5	3.2	4.2	3.1	1.5	3.9

**Table 11. Summary of Mean Log Reduction of PHMB Formulation.
6 months, 40 °C**

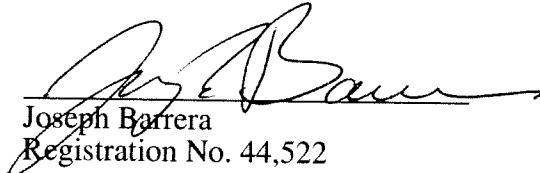
mean trial nos.	t (hr)	Sa	Pa	Sm	Ca	Fs	Fs t ₀
1/2 PET	1	4.7	3.3	2.0	2.8	2.3	2.0
	4	4.7	4.8	4.5	3.2	2.2	3.4
3/4/5 PET	1	3.5	4.0	3.4	3.0	1.2	2.7
	4	4.8	4.8	4.7	3.9	2.5	3.6
6/7/8 HDPE	1	1.5	2.8	2.5	1.5	0.3	1.5
	4	2.5	4.6	4.7	2.3	0.6	3.9

With respect to the prior use of an article of manufacture that includes the use of a PET container to store and package a lens care solution, Applicants submit that the lens care solution did not contain poly(hexamethylene)biquanide, but instead, polyquaternium-1. A PET container was used by Alcon Laboratories, Inc. to package a multipurpose lens care solution sold in the U.S. under the tradename OptiFree® Express more than one-year before the filing date of the present patent application. Nevertheless, Applicants submit that the claims are nonobvious over this prior use for the very same reasons the claimed article is novel and inventive over Groemminger in view of Asgharian. As noted, the Asgharian patent is assigned to Alcon Laboratories, Inc. (Alcon), and thus, describes the polyquaternium-1 lens care solutions that are marketed and sold by Alcon. Accordingly, the stated prior use of Alcon's PET container is merely cumulative to what is already described and cited in the Asgharian Patent.

For the reasons stated, Applicants respectfully request that the rejection be withdrawn.

Dated: January ⁸~~25~~, 2008

Respectfully submitted,



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